



Docket No. 212/291

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

In re Application of:

Mollenauer, et al.

Serial No.: 09/724,325

Filed: November 28, 2000

For: Resuscitation Device

Art Unit: 3764

Examiner: DeMille, D.

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DECLARATION UNDER 37 CFR 1.132

I, David R. Kamlan, hereby declare:

1. I am currently employed as a clinical education and training coordinator at Revivant Corporation. I am a licensed paramedic in the State of California and I am licensed to train paramedics and emergency medical technicians (EMTs) in the State of California. I have 7 years of experience as an EMT, 6 years of additional experience as a paramedic and 12 total years of experience training EMTs and 5 total years of training paramedics. Any other credentials are listed here or in the attached resume.

2. I am acutely aware of the state of the art in field techniques for treating patients in cardiac arrest. I am acutely aware of the contents of the Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (Guidelines 2000) published by the American Heart Association (ACLS Guidelines).

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3. I have reviewed Lach et al., Resuscitation Method and Apparatus, United States Patent 4,770,164 (Sep. 13, 1988), the Appeal Brief and the Examiner's Answer in this case.

4. The Examiner's Answer states that, "the shirt [shown in Figure 1 of Lach] would function as a friction liner at least to a certain extent." The Examiner's Answer also states that, "one of ordinary skill in the art would know that the shirt would act as a friction liner." Both of the Examiner's statements are incorrect. One of ordinary skill in the art would come to the opposite conclusion — that the shirt is a source of friction if a belt-driven chest compression device is applied to a patient wearing a shirt. Friction arises between the shirt and the patient's skin, between the patient's connective tissues, between the belt and shirt and between the belt and the skin while a belt-driven device is in operation. In practice, we have seen that in belt-driven resuscitation devices the shirt will exacerbate the frictional drag on the system and the frictional effects on the belt on the patient, leading to reduced battery life and lacerations or bruising on the patient. Thus, one of ordinary skill would have considered the shirt to be a source a friction and not a friction liner in any way. However, nobody in the art had any experience with this until Applicants had actually tried a belt-driven device on actual animals, cadavers and patients and so the solution to the problem was not foreseeable.

5. The Examiner states that, "This device [Lach] is intended for applying CPR and in emergency situations the EMTs are not going to be sizing the liner for different sized persons. The EMTs would be routinely applying the same sheet for each situation." This statement does not make sense because EMTs are

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trained to provide care appropriate to a patient's size during cardiopulmonary resuscitation. For example, EMTs of ordinary skill routinely and accurately gauge a patient's size for purposes of administering drugs and defibrillating shocks and for using differently sized needles, endotracheal tubes and defibrillation paddles. In particular, resuscitative devices are provided in juvenile and infant sizes and EMTs routinely select these devices for use as appropriate. If differently sized sheets were provided in Lach's device (assuming Lach's device was otherwise modified) then an EMT of ordinary skill would be able to gauge a patient's size and use an appropriately sized sheet in conjunction with Lach's device during a cardiac arrest emergency. The Examiner's suggestion to the contrary is incorrect given the common practice of selecting numerous emergency care implements based on patient size.

6. Belt-driven chest compression devices for use with children, infants and very small patients must be differently sized than similar devices sized for average-sized patients. Belt-driven chest compression devices for use with very large (thoracic circumference of over 52") or very obese patients (over 300 pounds) must be differently sized than similar devices sized for average-sized patients. In fact, our commercial device is not FDA approved for use with children because it is not appropriately sized.

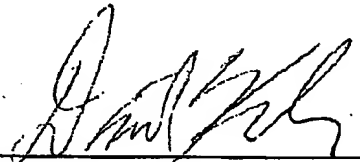
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the

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United States Code, and that such willful false statements may jeopardize the validity of the application, and any patent issuing thereon.

Date: June 7, 2004

By:



David R. Kamlan